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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,256	11/27/2000	R. Terry Dunlay	97,022-B1	5678

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1631	6

DATE MAILED: 05/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/723,256	Applicant(s) DUNLAY ET AL.	
	Examiner Nikolai M Galitsky	Art Unit 1631	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 30 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) [redacted] Pages 8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Group and/or Art Unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

Drawings

Applicant(s) is (are) hereby notified that the required timing for correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections with the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Information Disclosure Statement

The information disclosure statement filed 10/02/2001 has been entered and considered. An initialed copy of the PTO Form 1449 is enclosed with this action. There are two applications listed on page 8. Such applications have not been published nor have a data of publication and therefore cannot be properly listed on a form 1449. These applications have been considered.

Claim herein under examination is claim 30.

Provisional Obviousness-Type Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q. 2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); *In re*

Van Ornum, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970);and, *In re Thorington,* 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Claim 30 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 24 of co-pending Application No. 09/724,376. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims define an invention, which is a cell screening system to execute procedures for identifying or detecting actual activity of biomolecular complexes. Essentially, the art has introduced variation at random, perhaps in some cases with guidance from homology analyses to similarly-acting ligands or from analysis of fragments, e.g., trypsin digest fragments. Then the art has screened the candidates for the desired activity, e.g., agonist or antagonist activity. In particular, methods are needed for focusing on candidates likely to be either antagonists or agonists. Antagonists are substances that suppress, inhibit or interfere with the biological activity of a native ligand, while agonists exhibit greater activity per se than the native ligand. The aforementioned claim in the pending applications all provide systems,

methods, and screening with fluorescence-based molecular reagents and computer-based feature extraction, data analysis, and automation. Thus, with such similarity making the inventions have overlapping embodiments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Rejection Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30, lines 2 and 3, the program on the medium is directed to the identification of "novel receptor agonist and antagonist", but confusingly nothing in the system is directed to receptors, agonist, or antagonist. It this preamble controlling as to what the claimed subject matter is or are lines 3(last half) and 4-7 controlling what is being claimed? If lines 3(last half) and 4-7 control then there is not requirement for receptor practice, agonist, etc. If lines 1, 2, and 3(first half) are controlling then the cell screening system must contain receptors, agonist, etc. The claim is unclear which controls the subject matter. For example, one interpretation is that the identifying of novel receptor agonist etc. is doable with old standard equipment, which may be automated via said program. Clarification is required since the wording is unclear. Another interpretation is that such identification requires specifics such as receptors, some criteria for novelty, candidate agonists, candidate antagonists, etc. It is noted that the claim is also unclear as

to what criteria is applied for the identification of novel agonists or antagonists. Applicants can resolve this issue by particularly pointing out what kind of criteria is defined.

Claim 30, line 3 is cited "the sell screening system" without any receptor determination whatsoever. Are the cells required to have receptors under study on their surface? Nothing in the claim clarifies this issue. Is the agonist or antagonist determination performed via fluorescently labeled candidate molecule? Again the claim is unclear what is being screened in order to identify receptor agonist or antagonist.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 30 is rejected under 35 U.S.C. § 102(b) as being anticipated by Akong et al. (U.S. Patent No. 5,670,113. 23 September 1997).

Akong et al. describes an automated measurement apparatus and methods for automated drug screening and for studying ion channel and cell surface receptor activity are provided. The apparatus is designed to initiate and measure rapid or transient events, such as cell receptor and/or ion channel activity. The apparatus can effect measurements of transient reactions in or more samples in a multi-well container, initiate the reaction with reagent addition and measure a resulting attribute of the sample for a period of time. The apparatus is capable of substantially continuously measuring and recording data corresponding to the measured attribute before, during and after initiation of the reaction so that a time course of the rapid or transient event is

determined. Automated drug screening methods and methods for studying receptor and ion channel activity using the apparatus are also provided. The drug screening assays identify compounds that activate, inhibit or potentiate cellular ion channel or receptor activity (Abstract).

In such assays it is often required to determine the enzymatic activity of a number of samples and at one or more dilutions. Enzymatic reactions characteristically proceed at a constant rate provided substrate is present in large molar excess, i.e., the concentration of substrate does not limit the rate of reaction (Column 1, lines 25-30). In a particular aspect, the invention provides an automated method for rapid functional screening of compounds to identify potential pharmaceuticals, i.e., drugs. An efficient drug-screening method is provided which utilizes the computer-controlled fluorescence-measuring apparatus for rapid automated analysis of one or more compounds that is based on functional evaluation of drug targets, i.e., receptors and ion channels, in their physiological environment, i.e., living cells, in the presence of the potential pharmaceuticals. In the performance of the drug-screening assay, the sample wells contain receptor- and/or ion channel-expressing cells (Column 5, lines 20-21).

In an especially preferred embodiment, the cells are recombinant cells expressing a homogeneous population of recombinant receptors and/or ion channels thereby providing an assay which is valuable for determining the specificity of a compound having putative agonist or antagonist activity with respect to the receptors (Column 5, lines 45-51). The fluorescence of the solution in a given well can be measured a number of times and digital values representing each measurement are generated and stored (Column 7, lines 7-10). Lens also collects light emitted from a well at the sample point beneath mounting surface and couples the light so collected to a fiber optic cable. A software-controllable emission optical filter couples a selected range of

wavelengths of the light conveyed by fiber optic cable to a photo-multiplier tube via a fiber optic cable. The magnitude of the light conveyed by fiber is converted to an analog electrical signal from which a digital light amplitude representation is periodically generated (Column 7, lines 25-34). The multi-well plate is carried in assay apparatus by a plate-carrier system which moves plate in a rectangular coordinate manner to place any of the wells under the exciter/sampler or under the fluid tip responsive to plate movement commands from micro-computer (FIG. 3). Assay apparatus includes an assay controller, which is connected to microcomputer by bi-directional bus (FIG. 4) (Column 7, lines 45-52). The fluorescence of the sample in the predetermined well is measured using a filter and a photomultiplier tube or photodiode array or a charge coupled device (CCD)[which is certain type of digital camera] to detect emitted light, again in response to computer control, while the predetermined well is aligned with the measurement position. Advantageously, the measurement equipment may comprise a light source and filters for stimulating fluorescence and a photomultiplier tube (or photodiode array or CCD) to detect light emitted by the sample in the predetermined well using fiber optic cables to send and receive light (Column 3, lines 36-46).

In the preferred embodiment, the measured values are first stored within a microcomputer, which comprises the controller, and later moved to a disk drive for long-term storage. The microcomputer may be further equipped with data analysis programs that transform the data into relevant statistics and/or display the data in various formats (Column 3, lines 22-27).

Thus, Akong et al. clearly anticipates the instantly claimed invention.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Akong et al. in view of Lee et al. (US Patent 5,627,908. 06 May 1997).

Akong et al. teaches the fluorescence of the sample in the predetermined well is measured using a filter and a photomultiplier tube or photodiode array or a charge coupled device (CCD) to detect emitted light, again in response to computer control, while the predetermined well is aligned with the measurement position, however, Akong et al. fails to describe certain types of digital camera.

Lee et al. describes a digital camera attached to a microscope as shown in FIGS. 1A, 1B and 1C. The image acquired by the camera is of the cytologic specimen, magnified by an objective lens of 20.times. magnification. The camera digitizes the image to 512 by 512 pixels to a depth of 8 bits. The magnification of 20.times. and an image size of 512 by 512 pixels is by way of example and not limitation, and one skilled in the art will appreciate that other. magnifications and image sizes may be used without departing from the scope of the invention (column 28, lines 19-27). Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Akong et al., an automated measurement apparatus and methods for automated drug screening controlled by computer to use modern digital equipment such as CCD or such as Lee et al. the digital camera for an image analysis system.

Although the invention is not identically disclosed or described as set forth 35 U.S.C. 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a designer having ordinary skill in the art to which said subject matter pertains, the invention is not patentable.

No Claims Are Allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai M Galitsky, Ph.D., whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Williams Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 11, 2002

ARDIN H. MARSCHEL
PRIMARY EXAMINER